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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,283	03/29/2001	Richard B. Greenwald	213.1116-U	6788

7590 02/03/2003

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EXAMINER
RILEY, JEZIA

ART UNIT	PAPER NUMBER
1637	4

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,283	GREENWALD ET AL.	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17-21 and 23-31* is/are rejected.

7)☒ Claim(s) *16 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Remarks

1. Applicants' arguments and amendments, filed on 10/08/02, have been approved and entered. They have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 09/823,296. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common embodiments but not of the same scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants argue that the invention of the instant applicatin is not identical to th ecopending application because the G moiety in the copending application is not directly attached to the extender moiety. And as opposed to the instant application it is attached through the N-(E4)-J group. This is not convincing because if one reads the instant claim 1 for example, one could see that the M2 group can be a NR10 moiety and which is viewed to be inclusive of the N-E4 moiety. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-15, 17-20, 23-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al. (US 5,620,689).

Allen et al. discloses a method of treating a subject having a disorder characterized by a neoplasm of B-lymphocyte or T-lymphocyte lineage. The method includes administering a suspension of liposomes having a surface coating of polyethylene glycol chains. Attached to the distal ends of the chains are antibodies or antibody fragments effective to bind to an antigen specific to the affected cells. In one embodiment, anti-CD19 antibodies are attached to the liposome-bound chains, for treatment of multiple myeloma. FIGS. 2A-2B show steps of one synthetic approach for

forming a maleimide of a DSPE carbamide of polyethylene glycol his (amine) which can be used for further coupling to an antibody or antibody fragment. The figures 2A-4 are viewed to be inclusive of formula (I), instant claims 4-14 where the integers are defined.

The liposome includes an antibody or an antibody fragment, such as antibody 16, which is bound to the outer liposome surface by covalent attachment to hydrophilic polymer chains, such as chains 20, which are also carried on the liposome's outer surface. The polymer chains form a polymer layer about the liposome surface which allows the liposomes to circulate in the bloodstream over an extended period of time compared to liposomes lacking the polymer coating. The antigen recognition region, such as antigen recognition region 22, of the antibody molecule is accessible for binding to antigens at a target site. The polymer coating on the liposome surface does not affect antigen-antibody interactions. Antibody molecules suitable for use in the invention, and methods of their attachment to the liposome are described. The polymer chains are preferably polyethylene glycol (PEG) chains having molecular weights between about 500 and 10,000 daltons, corresponding to polymer chain lengths of about 22 to 220 ethylene oxide units. Preferably the PEG molecular weight is between 500-5,000 daltons, most preferably between 500-2,000 daltons. The polymer chains are covalently attached to the polar head groups of vesicle-forming lipids. The polymer chain is attached to the liposome through the polar head group of a lipid, such as lipid 18, in the outer layer 10 of the liposome bilayer. The chain contains a reactive functionalized group at its free end for coupling to the antibody.

Applicants argue that the reference does not suggest the instant application because the present invention employs either polymer residues that are capped on one end or homobifunctionel polymers. This is not convincing because instant claim 1 is silent as to what exactly what type of polymer is used. Instant claim 1 does not mentioned any capping or if the polymers are homobifunctional. What instant claim 1 says is that G is a linear or branched polymer residue.

5. Claims 16 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 31, 2003

JEZIA RILEY
PRIMARY EXAMINER